DEPARTMENT OF VETERANS AFFAIRS **8320-01**

38 CFR Part 17

RIN 2900-AQ31

Elimination of Copayment for Opioid Antagonists and Education on Use of Opioid Antagonists

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its medical regulations that govern copayments to conform with recent statutory requirements. VA would be eliminating the copayment requirement for opioid antagonists furnished to veterans who are at high risk of overdose of a specific medication or substance in order to reverse the effect of such an overdose. VA would also clarify that no copayment would be required for the provision of education on the use of opioid antagonists. This proposed rule would be an essential part of VA's attempts to help veterans at high risk of overdose.

DATES: Comments must be received on or before [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Comments may be submitted through www.Regulations.gov. Comments received will be available at regulations.gov for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Director of Policy and Planning. 3773 Cherry Creek North Drive, Denver, CO 80209. (303) 370–1637. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

In an effort to reduce the incidence of overdose among the veteran population, Congress, in two separate statutes, has required that VA must exempt from co-payment (1) opioid antagonists furnished under chapter 17 to a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose, and (2) education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances. See Pub. L. 114-198, sec. 915 (July 22, 2016) and Pub. L. 114-223, sec. 243 (Sept. 29, 2016). These provisions were effective upon enactment and have already been implemented. These provisions assist veterans by eliminating copayments for life-saving medication and education on the use of such medication, with the goal of reducing the incidence of overdose deaths among the veteran population. This proposed rule would amend two of VA's copayment regulations, 38 CFR 17.108 and 17.110, to accurately implement these changes in law. This proposed rule would also add an explanation of how VA would identify a veteran at high risk for overdose under the new provisions.

17.108 Copayments for inpatient hospital care and outpatient medical care.

Section 17.108 establishes the copayment amounts for inpatient hospital care and outpatient medical care. Paragraph (e) lists the types of services that are exempt from the inpatient hospital care and outpatient medical care copayment. We are proposing to add a new paragraph (e)(18) to implement the laws described above. Under paragraph (e)(18), we clarify that VA will not charge a copayment for an outpatient medical care visit that is solely for education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances. We note that while VA is not currently charging copayments for education on the use of opioid antagonists (in accordance with Public Law 114–198), codifying this in regulation will help ensure this policy continues to be followed. We also propose two minor conforming technical amendments to paragraphs (e)(16) and (e)(17) in section 17.108.

17.110 Copayments for medication.

Section 17.110 establishes the copayment amount for medications. Paragraph (c) lists the medications that are not subject to the copayment requirement. To implement section 915 of the Public Law 114-198, we propose adding a new paragraph (c)(12) to state that VA will not charge a copayment for opioid antagonists furnished to a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose. In paragraph (c)(12), we would also incorporate a definition of a high risk veteran for overdose for the purposes of this proposed rule. The proposed definition specifies that VA considers a high risk veteran for overdose to be a veteran who is prescribed or using opioids or has an opioid use history, and who is at increased risk for opioid overdose as determined by VA or whose provider deems,

based on their clinical judgment, that the veteran may benefit from ready availability of an opioid antagonist. We would also provide the following examples of a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose: A veteran with an opioid or substance use disorder diagnosis; a veteran receiving treatment for an opioid or substance use disorder diagnosis, such as receiving opioid agonist therapy or inpatient, residential, or outpatient treatment for such diagnosis, or attending a support group for such diagnosis; a veteran with a history of prescription opioid misuse or injection opioid use; a veteran with a history of previous opioid overdose; a veteran who is taking an extended-release or long-acting prescription opioid; a veteran with household or community access to opioids who is at increased risk for overdose (e.g., psychiatric disorder or high risk for suicide) as determined by VA; a veteran predicted to be at high risk for overdose based on standardized assessments or predictive models (e.g., Risk Index for Overdose or Serious Opioid-induced Respiratory Depression [RIOSORD], Stratification Tool for Opioid Risk Mitigation [STORM]); and a veteran in any of the aforementioned groups with a period of abstinence from opioids (e.g., due to treatment, detoxification, incarceration) as loss of tolerance can increase risk for overdose. This definition is necessary for VA to implement Public Laws 114-198 and 114-223. Public Laws 114-198 and 114-223 do not define a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose; however, providing a definition will facilitate the identification of such veterans. Early identification of these veterans can facilitate provision of life-saving opioid antagonist medication.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The adoption of the rule would not directly affect any small entities. There are no small entities involved with VA's process and/or adjustment of Veterans copayments for medications/services. The provisions of this rulemaking only apply to the internal operations of VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and

Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at http://www.va.gov/orpm/, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under EO 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number and title for this proposed rule are as follows: 64.009, Veterans Medical Care Benefits; 64.012,

Veterans Prescription Service; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.041, VHA Outpatient Specialty Care; 64.045, VHA Outpatient Ancillary Services; 64.047, VHA Primary Care; 64.048, VHA Mental Health Clinics.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on October 29, 2020, for publication.

***Consuela Benjamin**,*

Regulations Development Coordinator,

Office of Regulation Policy & Management,

Office of the Secretary,

Department of Veterans Affairs.

For the reasons set forth in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as set forth below:

PART 17 -- MEDICAL

1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

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2. Amend § 17.108 by revising paragraphs (e)(16) and (17) and adding (e)(18) to read as follows:

§ 17.108 Copayments for inpatient hospital care and outpatient medical care.

* * * * *

(e) * * *

(16) In-home video telehealth care;

(17) Mental health peer support services; and

(18) An outpatient care visit solely for education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances.

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4. Amend § 17.110 by adding a new paragraph (c)(12) to read as follows:

§17.110 Copayments for medication.

* * * * *

(c)* * *

(12) Opioid antagonists furnished to a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose.

(i) For purposes of this paragraph (c)(12), a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose is a veteran:

(A) Who is prescribed or using opioids, or has an opioid use history, and who is at increased risk for opioid overdose as determined by VA; or

(B) Whose provider deems, based on their clinical judgment, that the veteran may benefit from ready availability of an opioid antagonist.

(ii) Examples of a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose include, but are not limited to, the following:

(A) A veteran with an opioid or substance use disorder diagnosis;

(B) A veteran receiving treatment for an opioid or substance use disorder diagnosis, such as receiving opioid agonist therapy or inpatient, residential, or outpatient treatment for such diagnosis, or attending a support group for such diagnosis;

(C) A veteran with a history of prescription opioid misuse or injection opioid use;

(D) A veteran with a history of previous opioid overdose;

(E) A veteran who is taking an extended-release or long-acting prescription opioid;

(F) A veteran with household or community access to opioids who is at increased risk for overdose (e.g., psychiatric disorder or high risk for suicide) as determined by VA; or

(G) A veteran predicted to be at high risk for overdose based on standardized assessments or predictive models (e.g., Risk Index for Overdose or Serious Opioid-induced Respiratory Depression [RIOSORD]; Stratification Tool for Opioid Risk Mitigation [STORM]).

Note 1 to paragraph (c)(12). The examples in § 17.110(c)(12)(ii)(A) through (G) apply even if the veteran has had a period of abstinence from opioids (e.g., due to treatment, detoxification, incarceration) because loss of tolerance can increase the risk for an overdose.

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